

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL) ) MDL No. 16-2740  
PRODUCTS LIABILITY )  
LITIGATION ) SECTION: “H” (5)  
)  
This document relates to: )  
Barbara Earnest, 16-17144 )

**ORDER AND REASONS**

Before the Court is Plaintiff’s Motion to Exclude Dr. Shapiro’s and Dr. Smart’s Stem Cell Opinions (Doc. 7322). The Court held oral argument on the Motion on July 25, 2019. For the following reasons, the Motion is **DENIED** and **DEFERRED**.

**BACKGROUND**

Plaintiffs in this multidistrict litigation (“MDL”) are suing several pharmaceutical companies that manufactured and/or distributed a chemotherapy drug, Taxotere or docetaxel,<sup>1</sup> that Plaintiffs were administered for the treatment of breast cancer or other forms of cancer. Plaintiffs allege that the drug caused permanent alopecia—in other words, permanent hair loss. Plaintiffs bring claims of failure to warn, negligent misrepresentation, fraudulent misrepresentation, and more. The first bellwether trial of Plaintiff Barbara Earnest (“Plaintiff”) is set to begin September 16, 2019.<sup>2</sup>

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<sup>1</sup> Docetaxel is the generic version of Taxotere.

<sup>2</sup> To the extent the Motion relates to Plaintiff Tanya Francis, the Motion is moot, given the Court’s dismissal of her case.

## **LEGAL STANDARD**

The admissibility of expert testimony is governed by Federal Rule of Evidence 702, which provides as follows:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.<sup>3</sup>

The current version of Rule 702 reflects the Supreme Court's decisions in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*<sup>4</sup> and *Kumho Tire Co. v. Carmichael*.<sup>5</sup> The threshold inquiry in determining whether an individual may offer expert testimony under Rule 702 is whether the individual has the requisite qualifications.<sup>6</sup> After defining the permissible scope of the expert's testimony, a court next assesses whether the opinions are reliable and relevant.<sup>7</sup> As the "gatekeeper" of expert testimony, the trial court enjoys broad discretion in determining admissibility.<sup>8</sup>

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<sup>3</sup> FED. R. EVID. 702.

<sup>4</sup> 509 U.S. 579 (1993).

<sup>5</sup> 526 U.S. 137 (1999).

<sup>6</sup> *Wagoner v. Exxon Mobil Corp.*, 813 F. Supp. 2d 771, 799 (E.D. La. 2011); *see also* *Wilson v. Woods*, 163 F.3d 935, 937 (5th Cir. 1999) ("A district court should refuse to allow an expert witness to testify if it finds that the witness is not qualified to testify in a particular field or on a given subject.").

<sup>7</sup> *See* *United States v. Valencia*, 600 F.3d 389, 424 (5th Cir. 2010). *See also* *Wellogix, Inc. v. Accenture, L.L.P.*, 716 F.3d 867, 881–82 (5th Cir. 2013).

<sup>8</sup> *Wellogix*, 716 F.3d at 881.

First, to assess reliability, a court considers whether the reasoning or methodology underlying the expert's testimony is valid.<sup>9</sup> The party offering the testimony bears the burden of establishing its reliability by a preponderance of the evidence.<sup>10</sup> Courts should exclude testimony based merely on subjective belief or unsupported speculation.<sup>11</sup> Courts must, however, give proper deference to the traditional adversary system and the role of the jury within that system.<sup>12</sup> "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."<sup>13</sup> After assessing reliability, a court evaluates relevance.<sup>14</sup> In doing so, a court must determine whether the expert's reasoning or methodology "fits" the facts of the case and will thereby assist the trier of fact in understanding the evidence.<sup>15</sup>

### **LAW AND ANALYSIS**

In the instant Motion, Plaintiff asks the Court to exclude testimony from Defendants' experts Dr. Jerry Shapiro and Dr. Chandra Smart. Dr. Shapiro is a dermatologist, and Dr. Smart is a dermatopathologist. Plaintiff first argues that the doctors are not qualified to interpret certain stem cell testing because they are not stem cell experts. Plaintiff next argues that the doctors' opinions are unreliable because they rest on incorrect assumptions, specifically: (1) that Ki-67 and Cytokeratin 15 staining is a reliable method for identifying stem cells in the bulge of the hair follicle, and (2) that the presence of stem cells in this region means that hair loss is not permanent.

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<sup>9</sup> See *Daubert*, 509 U.S. at 592–93.

<sup>10</sup> See *Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 276 (5th Cir. 1998).

<sup>11</sup> See *Daubert*, 509 U.S. at 590.

<sup>12</sup> See *id.* at 596.

<sup>13</sup> *Id.*

<sup>14</sup> *Burst v. Shell Oil Co.*, 120 F. Supp. 3d 547, 551 (E.D. La. June 9, 2015).

<sup>15</sup> *Id.*

The Court rejects Plaintiff's argument that these experts are not qualified because they are not stem cell experts. First, Dr. Shapiro has specialized knowledge that would assist a trier of fact. Through his decades of experience as a doctor, he has gained an understanding of stem cell testing. He testified about this at his deposition:

Q: Do you -- did you make any attempt to search the peer-reviewed literature to see if cytokeratin-15 was or was not a reliable test for stem cells in the hair follicle bulge region before authoring your supplemental report?

A: As a doctor who has devoted his -- his three years -- 30 decades -- sorry. Three decades of work and when stem cells were first discovered I remember when that all came to be, and I remember these stains were important stains. But I did not look up the latest or anything like that.

All I know is that they help identify stem cells. They also help to identify proliferation of stem cells. But I don't know the latest literature on it. It may all be refuted.

Q: Do you know any literature?

A: Yeah. From a long time ago.

Q: I noticed in your supplemental report you didn't reference any scientific literature about cytokeratin-15. Why was that?

A: I thought it was a basic assumption. I really did. That it was a sign for stem cells.<sup>16</sup>

Dr. Shapiro may not be a "stem cell expert," but the Fifth Circuit has written that "[a] lack of specialization should generally go to the weight of the evidence, rather than its admissibility."<sup>17</sup> An expert witness "is not strictly confined to his area of practice, but may testify concerning related applications."<sup>18</sup> If Dr.

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<sup>16</sup> Doc. 7473-4 (pp. 213–14 of transcript).

<sup>17</sup> *United States v. Wen Chyu Liu*, 716 F.3d 159, 168–69 (5th Cir. 2013) (quoting *Wheeler v. John Deere Co.*, 935 F.2d 1090, 1100 (10th Cir. 1991)).

<sup>18</sup> *Id.*

Shapiro relies on outdated information, Plaintiff can illuminate this for the jury on cross-examination.

Similarly, while Dr. Smart may not be a “stem cell expert,” she is qualified to read and understand the results of Plaintiff’s stem cell stains. She testified that she is “an expert in reviewing immunohistochemical stains on tissue” and that she knows how to read whether Cytokeratin 15 staining is positive or negative.<sup>19</sup> She further testified that she uses Ki-67 stains in her daily practice to assess the proliferation rate of tumors.<sup>20</sup> This specialized knowledge renders Dr. Smart qualified to opine on Plaintiff’s testing.

Plaintiff next argues that the doctors’ opinions are unreliable because they rest on two incorrect assumptions—(1) that Ki-67 and Cytokeratin 15 staining is a reliable method for identifying stem cells in the bulge of the hair follicle, and (2) that the presence of stem cells in this region means that hair loss is not permanent. In support of this argument, Plaintiff points to deposition testimony from the two doctors—Dr. Shapiro stated that he does not know how reliable stem cell staining is, and Dr. Smart stated that Ki-67 is not a reliable test for the presence of stem cells. While Dr. Smart stated that Cytokeratin 15 is generally reliable in detecting stem cells, Plaintiff notes that her report contains no reference to any scientific literature that supports the reliability of using Cytokeratin 15 in identifying follicular stem cells.

What Plaintiff glosses over, however, is the fact that her own general causation expert credited this stem cell theory. The expert, Dr. Ellen Feigal, wrote as follows in her report:

Permanent, irreversible hair loss due to chemotherapy (PCIA) is thought to be likely a result of the hair follicle being permanently

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<sup>19</sup> Doc. 7473-5 (p. 157 of transcript).

<sup>20</sup> *Id.* (pp. 180–81 of transcript).

damaged, and the hair density is markedly reduced. This is thought to be likely due to irreversible damage of the stem cells.<sup>21</sup>

Dr. Feigal testified that Taxotere “may be poisoning the stem cells so that once that hair is lost, it’s lost” and the hair loses its “renewal capability.”<sup>22</sup> She stated that Taxotere is “probably somehow attacking the stem cell and irreversibly either damaging it, destroying it or perhaps interfering with its signaling pathway so that it can’t do what it needs to do.”<sup>23</sup>

Plaintiff also downplays the fact that her experts conducted the stem cell staining at issue. One of Plaintiff’s experts, Dr. Curtis Thompson, testified that if the results of the test had been negative, he would have pursued further testing. The results, however, were positive, evincing that Earnest’s stem cells were present and proliferating. This deflates Plaintiff’s stem cell theory and explains why Plaintiff wishes to exclude testimony from Dr. Shapiro and Dr. Smart on the results of Earnest’s testing.

The Court rejects Plaintiff’s argument that the opinions of Dr. Shapiro and Dr. Smart are inadmissible because they rest on the “incorrect assumption” that Ki-67 and Cytokeratin 15 staining is a reliable method for identifying stem cells in the bulge of the hair follicle. This assumption was first made by Plaintiff’s experts. It was Dr. Thompson who chose to use Ki-67 and Cytokeratin 15 staining to test for the presence of stem cells. This speaks to the reliability of the testing and bolsters the testimony of Dr. Shapiro and Dr. Smart on their knowledge of the testing. This also tells the Court that Plaintiff’s issue is not with the reliability of the stem cell staining but instead with the conclusions of Dr. Shapiro and Dr. Smart. As the United States Supreme Court said in *Daubert*, however, “[t]he focus, of course, must be solely

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<sup>21</sup> Doc. 6163-20 at 37.

<sup>22</sup> Doc. 7513-2 at 20–22.

<sup>23</sup> *Id.*

on principles and methodology, not on the conclusions they generate.”<sup>24</sup> Accordingly, Defendants’ reliance on this so-called “incorrect assumption” is not a valid basis for excluding the doctors’ opinions.

The Court further rejects Plaintiff’s argument that the doctors rely on the “incorrect assumption” that the presence of stem cells means hair loss is not permanent. Plaintiff cannot have it both ways—she cannot embrace this science for purposes of general causation but denounce it as mere theory when Defendants proffer experts to interpret her stem cell staining. Plaintiff is relying on this theory to build her case. If the theory is credible enough for Plaintiff’s general causation expert, it is credible enough for Defendants’ experts to consider when evaluating Plaintiff’s testing. Accordingly, Defendants’ reliance on this so-called “incorrect assumption” is not a valid basis for excluding the doctors’ opinions.

The Court will allow Defendants to introduce Dr. Shapiro and Dr. Smart to opine on the results of Plaintiff Earnest’s stem cell staining. Their opinions will be helpful to the jury and will allow Defendants the opportunity to refute Plaintiff’s theory of causation. The Court cautions, however, that the testimony from these two experts should not be redundant. Under Rule 403, a court may exclude needlessly cumulative evidence.<sup>25</sup> Defendants suggest that Dr. Shapiro’s opinion builds upon Dr. Smart’s opinion,<sup>26</sup> in which case these opinions are both admissible. However, if the opinions are cumulative, the Court will revisit this issue and limit the testimony as appropriate. The Court further cautions that Defendants should not consider this ruling a license to

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<sup>24</sup> *Daubert*, 509 U.S. at 595.

<sup>25</sup> FED. R. EVID. 403.

<sup>26</sup> In a footnote, Defendants state that “it is standard industry practice for a dermatologist to send their biopsies to a dermatopathologist and then use the dermatopathologist’s report as part of their clinical diagnosis. . . . Dr. Shapiro, as a board certified dermatologist, is qualified to read Dr. Smart’s report on what the biopsies show and use the results as part of his overall opinion.” Doc. 7473 at 3.

argue that the stem cell testing was in any way a failed study. Defendants will be limited to a review of Plaintiff Earnest's slides only.

### **CONCLUSION**

For the foregoing reasons, **IT IS ORDERED** that Plaintiff's Motion to Exclude Dr. Shapiro's and Dr. Smart's Stem Cell Opinions (Doc. 7322) is **DENIED** and **DEFERRED**.

New Orleans, Louisiana this 29th day of August, 2019.

A handwritten signature in black ink, appearing to read "Jane Triche Milazzo", written over a horizontal line.

JANE TRICHE MILAZZO  
UNITED STATES DISTRICT JUDGE